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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/359.937	12/20/94	ILLUM	L EPC148C1

PATREA L. PABST
ARNALL, GOLDEN & GREGORY
2800 ONE ATLANTIC CENTER
1201 WEST PEACHTREE STREET
ATLANTA, GA. 30309-3400

15M1/1229

KISHORE, C. EXAMINER	
ART UNIT	PAPER NUMBER
1502	16

DATE MAILED: 12/29/95

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.
08/359,937

Applicant(s)

Illum

Examiner
Gollamudi S. Kishore

Group Art Unit
1502



☒ Responsive to communication(s) filed on 21 Sep 1995

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-28 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-28 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Part III DETAILED ACTION

The request for the extension of time and amendment filed on 9-21-95 are acknowledged.

Claims included in the prosecution are 1-28.

Double Patenting

The obviousness type double patenting of claims 1-10 (now extended to 15-16) and the non-statutory double patenting of claims 11-14 (now extended to claims 17-28) are maintained in the absence of a terminal disclaimer. Applicants' arguments that the method and system are not obvious over the claims in claims in the prior patent are not found to be persuasive since this rejection is based on the full disclosure of the prior patent as set forth in the previous action.

Claim Rejections - 35 USC § 112

1. Claims 6 and 22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to what applicants intend to convey by 'treated by heating'; treated for what?

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5, 11 and 13 for reasons of record, are rejected under 35 U.S.C. § 102(e) as being anticipated by Illum.

Applicants' arguments have been fully considered, but are not found to be persuasive. The amendment to the independent claims will not overcome the rejection because what is introduced is an intended use and furthermore, applicants have not conclusively established that the cromoglycate administered by the same way in Illum does not enter circulation and thus provide a systemic effect.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-28 for reasons of record, are rejected under 35 U.S.C. § 103 as being unpatentable over Illum (1986).

Claims 7-12, and 14, 23-26 for reasons of record, are rejected under 35 U.S.C. § 103 as being unpatentable over Illum (4'847'091) or Illum (1986) in view of Hanson et al or Salzman et al or vice versa.

Applicants' arguments have been fully considered, but are not found to be persuasive. Applicants argue that Illum does not teach particles of sizes less than 20

micrometers and in fact Illum teaches away by suggesting the use of particles of sizes 40-60 microns. The examiner disagrees and points out that the sizes of 40-60 refers to the swelled sizes and instant claims do not recite swelled sizes of less than 10 microns. Illum's particles are intended to deliver therapeutic drugs such as insulin; insulin is known to be used of diabetes and it would thus, be obvious to an artisan that Illum teaches intranasal delivery intended of systemic effect. With regard to unexpected results argued by applicants, as pointed out above, the sizes of 40-60 in Illum are swelled sizes and for a proper comparison showing unexpected results, a comparison must made with the unswelled sizes in Illum. Furthermore, significant improvement does not constitute unexpected results, but rather a routine experimentation by an artisan from Illum's suggestions regarding sizes on page 209, last four lines.

Applicants argue that nothing in Hanson or Salzman teaches or suggests the claimed formulation of microspheres of instant sizes. The examiner points out that these references were combined with the primary references to show the motivation for one of ordinary skill in the art to use surfactants; applicants provide no specific arguments regarding surfactant effect taught by these references.

2. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS

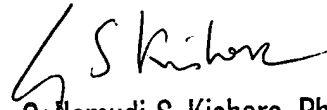
ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to G. S. Kishore whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K.Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-5408.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-2351.


Gollamudi S. Kishore, PhD
Primary Examiner
Group 1500

December 28, 1995